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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,763	08/07/2007	Judith Donovan	38-21(52949)B	6571

7590 07/24/2009  
Timothy K. Ball, Ph.D.  
Monsanto Company c/o Gail Wuellner  
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Mail Zone E2NA  
St. Louis, MO 63167

EXAMINER
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KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

MAIL DATE	DELIVERY MODE
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07/24/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,763	<b>Applicant(s)</b> DONOVAN ET AL.	
	<b>Examiner</b> Anne R. Kubelik	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 10, 11 and 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 9, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's election with traverse of Group XI (claims 8-9 and 12-13, to the extent they read on SEQ ID NO:4) in the reply filed on 12 June 2009 is acknowledged. The traversal is on the ground(s) that the problem to be solved is identification of polynucleotides encoding proteins that are different from those in the prior art and that encode lepidopteran toxins; the application thus exhibits unity because the subject matter related to a group of inventions so linked as to form a single general inventive concept. This is not found persuasive because this problem is not special; many others, including Schnepf et al (US Patent 6,107,278), cited in the restriction, has also done this. Applicant further urges that that the several proteins set forth in the application fulfills the unity requirement because there is a technical relationship among these inventions that involves one or more of the same corresponding special technical features; the genes and their proteins, with their lack of relationship to other genes and proteins in art, define a contribution over the prior art. This is not found persuasive because TIC402 does not define a contribution over the prior art; see art rejections below.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-7, 10-11 and 14-20 and sequences other than SEQ ID NO:4 are withdrawn from consideration as being drawn to nonelected inventions.

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless

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the references have been cited by the examiner on form PTO-892 or on the IDSs filed by Applicant, they have not been considered.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is directed to specific *Bacillus thuringiensis* strains. Since the strains are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the strains are not so obtainable or available, a deposit of the strains may satisfy the requirements of 35 USC 112. The specification does not disclose a repeatable process to obtain the strains and it is not apparent if the strains are readily available to the public. Thus, a deposit is required for enablement purposes.

If a deposit is made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, or someone empowered to make such a statement, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant

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may provide assurance of compliance by statement, affidavit or declaration, or by someone empowered to make the same, or by a statement by an attorney of record over his or her signature and registration number showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.801 - 1.809 [MPEP 2401-2411.05] for additional explanation of these requirements.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 9 is indefinite in its recitation of “EG5438”, given that a name does not clearly identify the claimed *B. thuringiensis* strain, and does not set forth the metes and bounds of the claimed invention. Since the name “EG5438” is not known in the art, the use of said name does not carry art recognized limitations as to the specific characteristics or essential characteristics that are associated with that denomination. In addition, the name appears to be arbitrary, and the specific characteristics associated therewith could be modified, as there is no written description

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of the strain that encompasses all of its traits. Amending the claims to recite an ATCC deposit number would overcome the rejection.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Carozzi et al (US Patent 7,355,099, filed February 2003).

Carozzi et al disclose a protein with 99% identity to the instant SEQ ID NO:4 (their SEQ ID NO:5). As the specification indicates that the name “TIC900” includes variants of SEQ ID NO:4 (¶136), the protein disclosed by Carozzi et al anticipates claim 8. As the name “EG5438” is indefinite for the reason indicated above, the protein disclosed by Carozzi et al anticipates claim 9.

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US-10-782-020A-5
; Sequence 5, Application US/10782020A
; Patent No. 7355099
; GENERAL INFORMATION:
; APPLICANT: Carozzi, Nadine
; APPLICANT: Hargiss, Tracy
; APPLICANT: Koziel, Michael G.
; APPLICANT: Duck, Nicholas B.
; APPLICANT: Carr, Brian
; TITLE OF INVENTION: AXMI-004, A Delta-Endotoxin Gene and
; TITLE OF INVENTION: Methods for Its Use
; FILE REFERENCE: 045600/274139
; CURRENT APPLICATION NUMBER: US/10/782,020A
; CURRENT FILING DATE: 2004-02-19
; PRIOR APPLICATION NUMBER: 60/448,810
; PRIOR FILING DATE: 2003-02-20
; NUMBER OF SEQ ID NOS: 11
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; SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 5
; LENGTH: 601
; TYPE: PRT
; ORGANISM: Bacillus thuringiensis
US-10-782-020A-5
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Query Match          99.0%; Score 3160; DB 3; Length 601;
Best Local Similarity 99.0%; Pred. No. 5.8e-283;
Matches 595; Conservative 2; Mismatches 4; Indels 0; Gaps 0;
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Qy      1 MNSKEHDYLVKVCNDLSDANINMERFDKNDAL EIGMSIVSELIGMIPGGTALQFVFNQLWS 60
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1 MNSKEHDYLVKVCNDLSDANINMERFDKNDAL EIGMSIVSELIGMIPGGTALQFVFNQLWS 60

Qy     61 RLGD SGWNAFMEHVEELIDTKIEGYAKNKALSELAGIQRNLETYIQLRNEWENDIENSKA 120
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     61 RLGD SGWNAFMEHVEELIDTKIEGYAKNKALSELAGIQRNLETYIQLRNEWENDIENSKA 120

Qy    121 QGKVANYYESLEQAVERSMPQFAVGNFEVPLLT VYVQAANLHLLLLRDVSVYGKRWGWSE 180
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    121 QGKVANYYESLEQAVERSMPQFAVENFEVPLLT VYVQAANLHLLLLRDVSVYGKCGWGWSE 180

Qy    181 QKIKIYYDRQIKYTHEYTNHCNVNWKGLERLKNKGSSYQDWYNNRFRREMTLTVLDIV 240
          |||||||:||||||||||||||||||||||||||||||||||||||||||||||
Db    181 QKIKIYYDKQIKYTHEYTNHCNVNWKGLERLKNKGSSYQDWYNNRFRREMTLTVLDIV 240

Qy    241 ALFFPHYDVQTYPI TTVAQLTREYVTDPLLNFNPKLHSVSQLPSFSDMENATIRTPHLM EF 300
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    241 ALFFPHYDVQTYPI TTVAQLTREYVTDPLLNFNPKLHSVSQLPSFSDMENATIRTPHLM EF 300

Qy    301 LRMLTIYTDWYSVGRNYYWGGHVRVTSYHVGGENIRSPLYGREANQEVPRDFYFYGPVFKT 360
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    301 LRMLTIYTDWYSVGRNYYWGGHVRVTSYHVGGENIRSPLYGREANQEVPRDFYFYGPVFKT 360

Qy    361 LSKPTLRPLQQPAPAPPFNLRSLLEGVEFHTSTG SFMYRERGSVDSFNELPPFPVGLPHK 420
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    361 LSKPTLRPLQQPAPAPPFNLRSLLEGVEFHTPTG SFMYRERGSVDSFNELPPFPVGLPHK 420

Qy    421 VYSHRLCHATFVRKSGTPYLTTGAIFSWTHRSABETNTIESNIITQIPLVKAYQIGSGTT 480
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    421 VYSHRLCHATFVRKSGTPYLTTGAIFSWTHRSABETNTIESNIITQIPLVKAYQIGSGTT 480

Qy    481 VRKGP GFTGGDILRRTGPGTFGDMRININAPLSERYRVRIRYASTTDLQFVTSINGATIN 540
          |||||||||||||||||||||||||||||||||||:|||||||||||||||||||
Db    481 VRKGP GFTGGDILRRTGPGTFGDMRININAPLSQRYRVRIRYASTTDLQFVTSINGTTIN 540

Qy    541 IGNFPKTINNLTGSEGYRTVSFSTPFSFSNAQSIFRLGIQAFSGVQEVYVDKIEFIPV 600
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    541 IGNFPKTINNLTGSEGYRTVSFSTPFSFSNAQSIFRLGIQAFSGVQEVYVDKIEFIPV 600

Qy     601 E 601
          |
Db     601 E 601
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***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 8-9 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carozzi et al (US Patent 7,355,099, filed February 2003).

The claims are drawn to a method of controlling lepidopteran pests with a protein of SEQ ID NO:4.

The teachings of Carozzi et al are discussed above. Carozzi et al do not teach a protein of SEQ ID NO:4 or a method of controlling a lepidopteran pests with it.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the protein taught by Carozzi et al to make the instant SEQ ID NO:4. One of ordinary skill in the art would have been motivated to do so because of the suggestion of Carozzi et al to make variants of their protein (column 11, line 40, to column 12, line 21). One of ordinary skill in the art would have been motivated to make the 6 amino acid substitutions required to convert Carozzi et al's protein to SEQ ID NO:4 because these amino acids substitutions are a conservative substitution (amino acid 514), substitutions suggested by Carozzi et al's Fig. 1 (amino acids 175, 189, 391 and 537), or are a substitution at a site that appears to tolerate any type of amino acid (amino acid 145).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to use the resulting modified protein to control lepidopteran pests. One of ordinary



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skill in the art would have been motivated to do so because of the suggestion of Carozzi et al to do so (column 19, line 5, to column 20, line 36, particularly, column 19, lines 61-66).

### *Conclusion*

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

July 24, 2009

/Anne R. Kubelik/

Primary Examiner, Art Unit 1638